L-TOPICAL BENZOYL PEROXIDE 10% GEL- benzoyl peroxide gel
GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

L-Topical BENZOYL PEROXIDE 10% GEL

DRUG FACTS

Active ingredient

Benzoyl peroxide 10%

Purpose

Acne treatment

Use

For the treatment of acne

Warnings

For external use only

Do not use if you • Have very sensitive skin • Are sensitive to benzoyl peroxide

When using this product • Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time. • Avoid unnecessary sun exposure and use a sunscreen • Avoid contact with the eyes, lips, and mouth • Avoid contact with hair and dyed fabrics, which may be bleached by this product • Skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

Stop use and ask a doctor if irritation becomes severe.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

• Clean the skin thoroughly before applying this product • Cover the entire affected area with a thin layer and rinse thoroughly one to three times daily • Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor • If bothersome dryness or

peeling occurs, reduce application to once a day or every other day. • If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

Other information

Store at 15°-30°C (59°-86°F).

Inactive ingredients

Allantoin, Aloe barbadensis leaf extract, Benzyl alcohol, Carbomer, Disodium EDTA, Disodium laureth sulfosuccinate, Glycerin, Panthenol, PEG-8, PPG-14 palmeth-60 hexyl dicarbamate, Sodium hyaluronate, Triethanolamine, Water

Questions?

Call toll-free 1-800-572-6632, Weekdays 7:00 AM - 5.30 PM EST.

✓ Acne Treatment

Manufactured by :

Global Pharma Healthcare Pvt. Ltd.,

A-9, SIDCO Pharmaceutical Complex,

Alathur-603 110 - INDIA.

www.global-pharma.com

Packaging

L-TOPICAL BENZOYL PEROXIDE 10% GEL

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73921-032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	100 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
DISODIUM LAURETH SULFOSUCCINATE (UNII: D6DH1DTN7E)	
GLYCERIN (UNII: PDC6A3C0OX)	
PANTHENOL (UNII: WV9CM0O67Z)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PPG-14 PALMETH-60 HEXYL DICARBAMATE (UNII: 376C96Y6AL)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:73921-032-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	04/01/2021	

Labeler - GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED (860186917)

Establishment

Name	Address	ID/FEI	Business Operations
GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED		860186917	manufacture(73921-032)